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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,014	AMIN ET AL.	
	Examiner	Art Unit	
	IQBAL H. CHOWDHURY	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-166* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☒ Claim(s) *4* is/are allowed.

6)☒ Claim(s) *1-2, 3, 5-7, 118, 134-135, 147-148, 155-158, 165 and 166* is/are rejected.

7)☒ Claim(s) *91,119 and 120* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/6/07, 6/6/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 8-90, 92-116, 117, 121-124, 126-133, 136-146, 149-154, 159-163 and 164 .

DETAILED ACTION

Application Status

This application is a 371 of PCT/US04/40438 filed on 12/3/2004.

Claims 1-166 are currently pending.

The preliminary amendment filed on 5/30/2006 is acknowledged.

Election/Restriction

Applicant's election with traverse of Group I claim(s) I-7, 91, 117-120, 125-126, 134-135, 147-156 and 157-166, drawn to an isolated natural perhydrolase enzyme in the response filed on 9/14/2010 is acknowledged.

The traversal is on the ground(s) that Group II is drawn to a modified perhydrolase enzyme, which could be readily be searched at the same time as the claims of Group I and Group I and II are linked by a common structural and functional characteristics, which is not persuasive because this application is 371, which follows PCT Restriction practice based on Special Technical feature, NOT US Restriction practice as argued. If the Special Technical feature is novel, then the Examiner would examine the product, process of making and process of use (three Groups). However, if the Special Technical feature is known in the prior art, all the inventions lack unity of invention. Besides, burden is not the criteria of Restriction practice of 371 and PCT applications. Furthermore, 37 CFR 1.475 does not provide for multiple products and/or methods within a single application. Therefore, all the inventions lack unity of invention.

The requirement is still deemed proper and is therefore made **FINAL**.

The Examiner noted that in the Restriction requirement mailed on 12/4/2009, claims 117, 126, 149-154, 159-163 and 164 that were included in group I, should have been included in

Group II, which drawn to modified perhydrolase enzyme, and thus, now, claims 117, 126, 149-155, 159-163 and 164 are placed with Group II and now, Group I comprises claims I-7, 91, 117-120, 125, 134-135, 147-148, 155-157 and 158.

Claims 8-90, 92-116, 117, 121-124, 126-133, 136-146, 149-154, 159-163 and 164 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims I-7, 91, 118-120, 125, 134-135, 147-148, 155-158, 165 and 166 are under consideration and are present for examination.

Priority

Acknowledgement is made of applicants claim for domestic priority under 35 USC 119(e) to provisional application 60/526,764 filed on 12/3/2003.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on 9/6/2007 and 6/6/2008 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are considered by the examiner. The signed copies of IDSs are enclosed herewith.

Drawings

Drawings submitted on 5/30/2006 are accepted by the Examiner.

Claim Objections

Claims 91 and 125 are objected to as depending from non-elected claims. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 3, 91 (which depends on claim 88), 155-156, 165 and 166 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is indefinite and vague in the recitation ""at least --- 35% homologous to said M. smegmatis perhydrolase", or "GDSL-GRTT, GDSL-ARTT, GDSN-GRTT, GDSN-ARTT and SDSL-GRTT", which is confusing because absent a reference to an amino acid sequence of the M. smegmatis perhydrolase to which "35 % homologous of amino acid sequence" or "GDSL-GRTT, GDSL-ARTT, GDSN-GRTT, GDSN-ARTT and SDSL-GRTT" refers? A 35% homologous sequence cannot be obtained or calculated without the amino acid sequence of the M. smegmatis perhydrolase protein. What is the sequence of M. smegmatis perhydrolase? Accordingly, claims 155-156, 165 and 166 are also rejected, as they depend on claim 3.

Claims 3, 155-156, 165 and 166 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is indefinite in the recitation "at least approximately about 35%" which is ambiguous and confusing. It is unclear whether applicant meant "at least 35%" or "about 35%" or "approximately 35%". However, "about 35%" and "approximately 35%" is unclear and vague, as it is not clearly stated in the specification about what is the scope of "about 35%" or "approximately 35%" mean? In addition, the combination of "at least approximately about 35%" is ambiguous and confusing.

Claims 1-2, 3, 5-7, 118, 134-135, 147-148, 155-158, 165 and 166 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to any isolated perhydrolase enzyme from any source or any M. smegmatis species, which is at least 35% homologous to M. smegmatis perhydrolase. The specification discloses the reduction of practice of several species of variants of M. smegmatis perhydrolase of SEQ ID NO: 2 having perhydrolase activity. There is no other drawing or structural formula disclosed of a perhydrolase polypeptides having 35% sequence homologous to perhydrolase polypeptide of SEQ ID NO: 2 from M. smegmatis and having perhydrolase activity. The specification does not contain any disclosure of any variants of M. smegmatis perhydrolase, which is 35% homologous to M. smegmatis perhydrolase of SEQ ID NO: 2 combined with pre-existing knowledge in the art regarding the genetic code and its redundancies would have put one in possession of the genus. With the aid of computer, one of skill in the art could identify all of the polypeptides with at least 35% sequence homologous to M. smegmatis perhydrolase of SEQ ID NO: 2. However, there is no teaching regarding which 65% of the amino acids can vary from SEQ ID NO: 2 and still result in a protein that retains perhydrolase activity. Furthermore, there is no disclosed or art-recognized correlation between any structures other than SEQ ID NO: 2 and having perhydrolase activity. While general knowledge in the art may have allowed one of skill in the art to identify other proteins expected to have the same or similar tertiary structure, in this example there is no general knowledge in the art about

perhydrolase activity to suggest that general similarity of structure confers the activity. Accordingly, one of skill in the art would accept the disclosure of SEQ ID NO: 2 as representative of other proteins having perhydrolase activity. The specification, taken with the pre-existing knowledge in the art of amino acid substitution and the genetic code, fails to satisfy the written description requirement under 35 USC 112, first paragraph.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-2, 3, 5-7, 118, 134-135, 147-148, 155-158, 165 and 166 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a perhydrolase enzyme polypeptide of SEQ ID NO: 2 from M. smegmatis and several variants of SEQ ID NO: 2, does not reasonably provide enablement for any perhydrolase enzyme from any source having any structure or from ant M. smegmatis species, which is at least 35% homologous to M. smegmatis perhydrolase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands (858 F.2d 731,737, 8 USPQ2nd 1400 (Fed. Cir. 1988)) as follows:

(1) quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence and absence of working examples, (4) the nature of the invention, (5) the state of prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The factors, which have, lead the

Examiner to conclude that the specification fails to teach how to make and/or use the claimed invention without undue experimentation, are addressed below:

The breadth of the claims:

Claims 1-2, 3, 5-7, 118, 134-135, 147-148, 155-158, 165 and 166 are so broad as to encompass any perhydrolase enzyme from any source having any structure or from ant M. smegmatis species, which is at least 35% homologous to M. smegmatis perhydrolase. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins including many mutants, variants and recombinants broadly encompassed by the claims. In the instant case the disclosure is limited to the nucleotide and encoded amino acid sequence of only a single protein of SEQ ID NO: 2 isolated from M. smegmatis and several variants of SEQ ID NO: 2.

The state of prior art, the relative skill of those in the art, and the predictability or unpredictability of the art:

The amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. In the instant case, the protein which is 35% homologous to any perhydrolase protein of M. smegmatis, i.e. 65% comprises many mutants, variants and recombinants. The art clearly teaches the high level of unpredictability with regard to the effect of structural changes in a protein's activity when no guidance/knowledge as to which amino acids are required for activity has been provided. While recombinant and mutagenesis techniques

are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. Whisstock et al. (2003) teach that prediction of protein function from sequence and structure is a difficult problem because homologous proteins often have different functions (see abstract). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions. Similarly, at the time of the invention, there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity. Similarly, Chica et al. (Curr Opin Biotechnol. 2005 Aug;16(4):378-84; PTO 892) teach that the complexity of the structure/function relationship in enzymes has proven to be a factor in limiting the general application of rational enzyme modification and design, where rational enzyme modification and design requires in-depth understanding of structure/function relationships. The teachings of Whisstock et al. and Chica et al. are further supported by the teachings of Witkowski et al. (1999), where it is shown that even small amino acid changes result in enzymatic activity changes.

The amount of direction or guidance presented and the existence of working examples:

The specification discloses a perhydrolase enzyme polypeptide of SEQ ID NO: 2 from M. smegmatis and several variants of SEQ ID NO: 2. However, the specification fails to provide any clue as to the structural elements required in any perhydrolase protein from any source or any M. smegmatis species and having 35% homologous to any perhydrolase protein from M.

smegmatis, i.e. 65% non-homologous to M. smegmatis perhydrolase protein known in the art that are essential for any protein to display perhydrolase enzymatic activity. No correlation between structure and function has been presented.

The specification does not support the broad scope of the claims which encompass any perhydrolase enzyme from any source having any structure or from ant M. smegmatis species, which is at least 35% homologous to M. smegmatis perhydrolase because the specification does **not** establish: (A) regions of the protein structure which may be modified without affecting perhydrolase enzymatic activity and; (B) the general tolerance of perhydrolase polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any perhydrolase polypeptide amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

The quantity of experimentation required practicing the claimed invention based on the teachings of the specification:

While methods of generating or isolating variants of a polynucleotide were well known in the art at the time of invention, it is not routine in the art to screen by trial and error process for (1) all or any protein which is 35% homologous to perhydrolase protein from M. smegmatis, (2) an essentially infinite number of mutants, variants and recombinants of any perhydrolase protein from M. smegmatis. The amino acids modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions. In addition, one skilled in the art would expect any

tolerance to modification for a given protein to diminish with each further and additional modification.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any perhydrolase enzyme from any source having any structure or from ant M. smegmatis species, which is at least 35% homologous to M. smegmatis perhydrolase. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any perhydrolase protein having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 118, 134-135, 147, 148, 157 and 158 are rejected under 35 U.S.C. 102(b) as being anticipated by Poulose et al. (Enzymatic peracid bleaching system with modified enzyme, US 5,108,457, issued on 4/28/1992, see IDS). The term perhydrolase defined in the specification ([0125] to an enzyme capable of catalyzing a reaction that results in the formation of sufficient amount of peracid, which has high perhydrolysis to hydrolysis ratio.

Poulose et al. teach a novel enzyme, which produces peracids by perhydrolysis, wherein said enzyme has both per-hydrolytically and hydrolytically active having lipase activity (lipase 1), whercin said cnzyme has higher ratio of peracid/acid than commercially available lipase. Poulose et al. also teach that a detergent composition comprising said enzyme and a substrate being capable of hydrolysis by said enzyme, which includes glycerides, an ester and a source of per-oxygen to produce peracid useful for bleaching as a cleaning bleaching composition. Poulose et al. further teach use of additional enzyme including lipase 2 different from lipase 1. Since, Poulose et al. teach a perhydrolase enzyme within the scope of the claim, perhydrolysis to hydrolysis ration greater than 1 is the inherent property of the enzyme (abstract, Col 2, paragraph2, Col 3, paragraph 1, Col 5, paragraph 2-5, Col 6, paragraph 3, Col 7, paragraph 4-6, Col 9, paragraph 5-7, and claims 1-15) Claim 2 is included in this rejection because functionally the enzyme of Poulose et al. and the instant application is same and thus, structurally is also same (inherently) as the perhydrolase from M. smegmatis, if there is any evidence in the contrary.

Therefore, Poulose et al. anticipate claims 1, 2, 118, 134-135, 147, 148, 157 and 158 of the instant application as written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poulose et al. (Enzymatic peracid bleaching system with modified enzyme, US 5,108,457, issued on 4/28/1992, see IDS) as applied to claims 1, 2, 118, 134-135, 147, 148, 157 and 158 above and further in view of UniProt Accession No. Q92XZ6, created 12/1/2001).

Poulose et al. teach an isolated novel enzyme, which produces peracids by perhydrolysis, wherein said enzyme has both per-hydrolytically and hydrolytically active having lipase activity (lipase 1), wherein said enzyme has higher ratio of peracid/acid than commercially available lipase. Poulose et al. also teach that a detergent composition comprising said enzyme and a substrate being capable of hydrolysis by said enzyme, which includes glycerides, an ester and a

source of per-oxygen to produce peracid useful for bleaching as a cleaning bleaching composition. Poulose et al. further teach use of additional enzyme including lipase 2 different from lipase 1. Since, Poulose et al. teach a perhydrolase enzyme within the scope of the claim, perhydrolysis to hydrolysis ration greater than 1 is the inherent property of the enzyme (abstract, Col 2, paragraph2, Col 3, paragraph 1, Col 5, paragraph 2-5, Col 6, paragraph 3, Col 7, paragraph 4-6, Col 9, paragraph 5-7, and claims 1-15) Claim 2 is included in this rejection because functionally the enzyme of Poulose et al. and the instant application is same and thus, structurally is also same (inherently) as the perhydrolase from M. smegmatis, if there is any evidence in the contrary. Poulose et al. do not a perhydrolase enzyme, which is 35% identical to SEQ ID NO: 2 of the instant application.

UniProt Accession No. Q92XZ6 teaches a hydrolase, which is 66% identical to instant application and perhydrolase activity is the inherent property of the polypeptide of Q92XZ6.

UniProt Q92XZ6 clearly teaches a hydrolase enzyme, which is 66% identical to SEQ ID NO: 2, inherently a perhydrolase enzyme. Poulose et al. clearly teach an isolated perhydrolase enzyme.

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole at the time of the invention was made by combining the teachings of Poulose et al. and UniProt Q92XZ6 to isolate the hydrolase enzyme of UniProt Q92XZ6, which is 66% identical to SEQ ID NO: 2, using the method of Poulose et al. to arrive the claimed invention.

One of ordinary skilled in the art would have been motivated to isolate the hydrolase enzyme because it would be easier to use said enzyme in detergent composition for cleaning

purpose, which is commercially and economically important.

One of ordinary skilled in the art would have a reasonable expectation of success because isolating an enzyme well known and widely used in the art in view of the technical skill of one of ordinary skilled in the art.

Thus, the above references render the claims *prima facie* obvious to one of ordinary skill in the art.

Conclusion

Status of the claims:

Claims 1-2, 3, 5-7, 118, 134-135, 147-148, 155-158, 165 and 166 are rejected.

Claim 4 is allowed.

Claims 91, 119 and 120 are objected to for depending on rejected base but would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 1st and 2nd paragraph, set forth in this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, Patent Examiner

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